NASA SBIR 2022 Phase I Solicitation

H12.07 Protective Pharmaceutical Packaging

Lead Center: JSC

Participating Center(s): ARC, GRC

Scope Title

Protective Medication Packaging Technologies Supporting Exploration Spaceflight Operations

Scope Description

Successful long-duration space exploration missions will require robust crew support systems. These systems will rely on exponentially increasing crew autonomy, operate in low-to-no logistical resupply settings, and facilitate independent decision making within the context of challenging communication scenarios due to limited to no terrestrial-based support asset reach back. In addition, the long-duration spaceflight environment will require medically trained crew members who can assess, diagnose, and treat each other for a variety of illnesses and injuries. These medical events will require the preselection and long-term storage of various medications onboard human crewed spacecraft or predeployed in advance of human missions. Although currently there is no available method to sufficiently characterize or quantify the pharmaceutical stability, quality, or potency of repackaged medications (stored and eventually utilized for human consumption during long-duration space flight missions), available data shows that the median risk of drug failure (based on U.S. Pharmacopeia (USP)Â acceptance thresholds) for a 2-year exploration mission is approximately 59%. This risk increases to about 82% for a 3-year mission. These factors expose the distinct possibility that the provision of safe and effective drug treatment of long-duration crew may be at significant risk due to the current operationally derived need to repack crew medications to reduce resource "costs" (i.e., mass, volume, and power) possibly adversely impacting crew wellness, performance, and long-term health.

While baseline instability has not been experimentally investigated, most of the pharmaceuticals tested in spaceflight studies to date have been removed (due to mass, volume, and power considerations) from manufacturer's containers and repackaged into either polypropylene container (Du et al. 2011) or lightweight, resealable plastic zipper storage bags. This type of repackaging remains the norm for supplying medications to the International Space Station (ISS). Unfortunately, such containers are not protective, therefore repackaged pharmaceuticals are exposed to ingress of atmospheric factors at concentrations in equilibrium with the ambient atmosphere (Putcha et al. 2016; Waterman et al. 2002). It is well established that such packaging is permeable to atmospheric factors such as moisture and oxygen and that prolonged exposure of susceptible medications is detrimental to shelf life (Roy et al. 2018; Waterman et al. 2002; Waterman et al. 2004).

Whereas exposure to spaceflight conditions (e.g., galactic cosmic radiation (GCR), microgravity,Â or zero-gravity, etc.) is only a minor factor contributing to the cumulative risk of drug failure,Â with the significant factor being the baseline risk (observed in paired terrestrial controls under similar environmental conditions), repackaging of pharmaceuticals likely reduces medication effectiveness significantly (and increasingly, as "out of package"

exposures extend in long-duration spaceflight), diminishes therapeutic effectiveness, thus potentially compromising crew health and performance.

In the past, repackaging methods have not been a significant limitation for missions where flight duration was much shorter than drug expiry (e.g., Apollo, Space Transport System (STS)) or where low Earth orbit permits regular replacement of expiring drugs (i.e., ISS). However, long-duration exposure of pharmaceuticals to atmospheric factors during exploration space missions will increase the risk of analytical drug failure over time, increasing the risk of therapeutic failure and potential exposure to toxicologically active impurities. Therefore, proven repackaging countermeasures are required to assure adequate stability of susceptible medications for the entire duration of exploration space missions.

This subtopic solicits proposals that address the critical need for exploring novel protective packaging technologies. Candidate technologies will retain or replicate (a) "initial" pharmaceutical packaging standards (i.e., minimization or elimination of atmospheric conditions), (b) acceptable shelf life (active pharmaceutical ingredient (API) minimums that meet or exceed Food and Drug Administration standards with respect to planned long-duration spaceflight timelines), (c) reduce reliance or need for cold storage/refrigeration of pharmaceuticals while, (d) preserving, optimizing, or reducing resource "costs" in regards to operational mass, volume, and power constraints (e.g., reducing power and mass requirements for an "in-vehicle" cold storage system), and (e) provide the potential for development of cross-cutting storage/repackaging technologies that integrate across, streamline, or expand the capabilities of multiple vehicle human support systems.

Expected TRL or TRL Range at completion of the Project

3 to 6

Primary Technology Taxonomy

Level 1

TX 06 Human Health, Life Support, and Habitation Systems

Level 2

TX 06.3 Human Health and Performance

Desired Deliverables of Phase I and Phase II

- Â PrototypeÂ
- Â HardwareÂ
- Â Software

Desired Deliverables Description

Drug packaging that minimizes mass, volume, and material waste and protects contents from ingress of atmospheric factors, including moisture, oxygen, and carbon dioxide.

Drug packaging technologies that help preserve APIÂ integrity and efficacy across exploration spaceflight mission durations with minimal (or reduced) mass/volume/power resource cost(s).

Phase I Deliverable â€“ Candidate packaging solutions.

Phase II Deliverable â€“ Experimentally demonstrated effectiveness under long-term (2-year) and accelerated conditions.Â

State of the Art and Critical Gaps

The state of the art of medication/pharmaceuticals packing technologies for exploration missions is uncertain. Foil

packaging is an industry standard for pharmaceutical products and ensures low moisture transmission. AclarÂ® films have similar low moisture transmission and can be layered with other materials to increase the barrier to gas permeation. Mylar Â® films have been used as a high barrier packaging to protect foods and bulk pharmaceutical ingredients from the effects of oxygen, moisture, and light. Such materialsâ€”possibly combined with purging packaging headspace with inert gas (argon) or nitrogenâ€”may be effective strategies to extend medication shelf life. Enclosing materials that scavenge oxygen, moisture (e.g., silica gels), and CO_2Â may offer additional advantages.

Relevance / Science Traceability

This subtopic seeks technology development that benefits the Exploration Medical Capability Element (ExMC) of the NASA Human Research Program (HRP). Pharmaceutical repackaging technologies are needed to address the following assigned risks:

- Risk of ineffective or toxic medications during long-duration exploration spaceflight.
- Risk of adverse health outcomes and decrements in performance due to inflight medical conditions.

and supports the following identified HRP Gaps:

- Pharm-101: "â€¦ determine the optimal packaging/storage strategy for medications in space that balances the needs of mitigating toxicity, preserving effectiveness, and minimizing resource "costs" (mass, volume, power, etc.)."
- Pharm-401: â€œâ€¦ perform further research to understand and characterize the active pharmaceutical ingredient and degradation profiles of medications for which we have low to moderate confidence in their safety and effectiveness for exploration missions.â€
- Pharm-601: â€œâ€¦ characterize the extent to which spaceflight alters pharmacokinetics and pharmacodynamics.â€

References

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- HRP Human Research Roadmap: Evidence Reports:Â https://humanresearchroadmap.nasa.gov/evidence/reports/Pharm.pdf?rnd=0.294621103114738

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